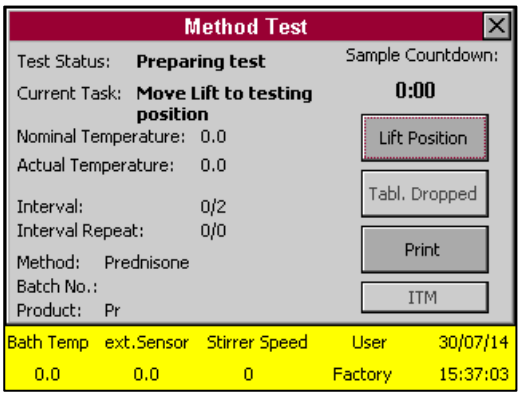
PTWS 820D – USP/EP Tablet Dissolution Testing Instrument

The PTWS 820D is an 8 position, single drive compact tablet dissolution testing instrument for solid dosage forms as described in USP chapter <711/724> and EP section<2.9.3/4> as well as the DAB and Japanese Pharmacopeia section <15>.

User Interface

In keeping with our cutting edge design, a large color, touch screen allows control of the various mechanical features of the instrument such as the tool stirring speed, lift drive and heater. The instrument control is menu driven. Visual signals on the display inform the user of the status of critical instrument parameters, e.g. bath target temperature not reached. Access to the instrument can be password controlled if required. If certain operational parameters form a regular feature of the daily routine, then these can be incorporated into a test method for faster set up. These parameters can be tool speed, target bath temperature, sampling time



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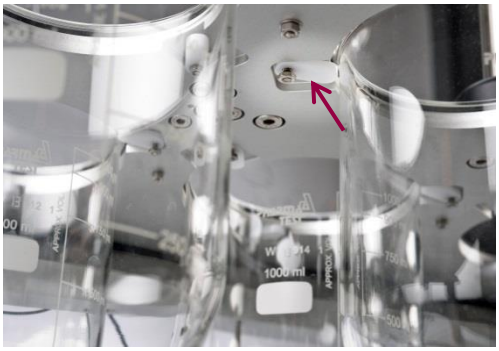
points and so on. The test method memory capacity is almost limitless. As soon as the test is started, a screen saver can be activated with the most important information displayed in large script so that this information remains visible even at time when the operator is not standing directly in front of the instrument.

Stirring Tools

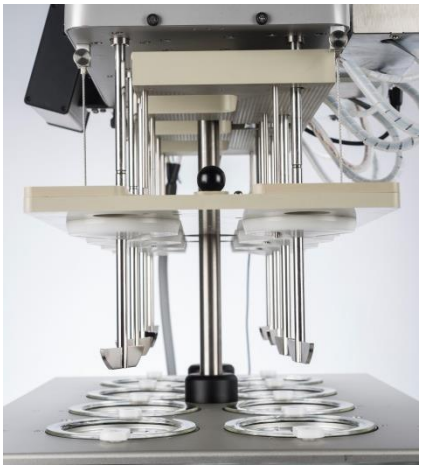
The PTWS 820D uses the Pharma Test MonoShaft™ design. Tools consist of the main shaft plus interchangeable tool heads (adapters). The main shaft remains in place in the instrument regardless of the tool head being used. The clearance of each tool from the vessel base will always be correct once the main tool shaft has been installed and qualified with any one of the tool sets once. Each stirrer can be raised by hand into a convenient position for easy vessel removal or insertion. PTWS 820D is capable to perform a staggered start for each of the eight positions.

Vessel Centering System

The PTWS 820D features a rigid and precise three-point individual centering system for each dissolution vessel (picture shows view from below). The vessels are held in position by three adjustable noses and are inserted into the instrument support framework. The access points for sampling as well as the openings for the tools are contained in an auxiliary, low evaporation, vessel cover. Each USP Borosilicate glass vessel has a batch code on top of the flange for easy visibility and positioned placement inside the water bath cover.



Lift Mechanism



The upper drive is motorized and electronically controlled it offers eight programmable positions: an upper cleaning and instrument qualification position and lower working positions are programmable depending on the type of stirring tool used. The upper position offers ideal access to the stirring tools and vessels for a change of tools and cleaning steps between the dissolution tests. The electronically driven lift mechanism is located centrally above the water bath. This ensures that the whole lift drive mechanism is positioned in a way so that the tool shafts are always kept parallel and at a 90° angle to the vessel walls when in the working position.

Heating System

The heating system is contained in a separate stainless steel housing. The connections between the heater and the bath are made by "quick connect fittings" for easy connection and disconnection. Water is pumped through the system using a powerful, yet quiet, circulation pump. The pump itself is spring mounted (to limit vibration transmission) and the flow-through heater is protected from overloading (overheating in case of control electronics failure) via a thermal fuse as well as a thermo switch for added security. With service and maintenance in mind, access to the compact pump and heater section is easily achieved without having to move the main body of the instrument.

Water Bath

The vacuum moulded water bath can easily be removed from the support frame for cleaning purposes. The bath cover can also be easily unscrewed for cleaning. The water bath contains a water diffuser for faster heating and to ensure that heated water is evenly distributed throughout the whole bath.

Space Requirements

A key point in today's crowded labs is the footprint of the PTWS 820D. The space saving design of the PTWS 820D offers the user the choice between a 2x4 or a 4x2 configuration with a minimal space requirement of just 45cm by 75cm (width by depth). The display module can be mounted either of two positions on the drive head of the PTWS 820D instrument.

Automation Capabilities

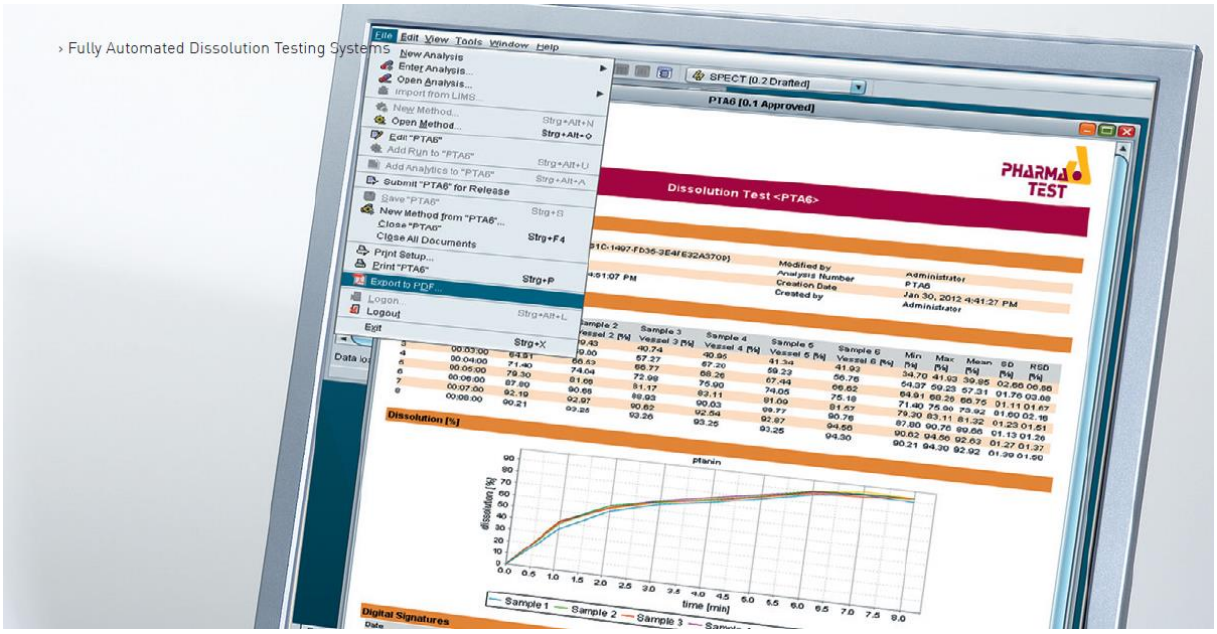
PTWS 820D offers the EPE-820 motorized sampling system which automatically lowers the sampling probes into the media vessels at the point of sampling and then raises them back out again. Up to 8 different sampling positions can be programmed to meet the different media levels inside the vessels. The ITM-820 individual media temperature monitoring system is attached to the EPE-820 and will read and report the media temperature while sampling. The vessel temperatures measured last can be re-called at any time. A manual TM or motorized TMA tablet dropping magazine is also available. This magazine includes low evaporation vessel sealing covers and magnetic holders for the tube cleaning device. The convex shape of the covers causes condensed medium to drop back into the dissolution vessels. PTWS 820D offers a complete the set of useful accessories for dissolution automation.

For offline automation with fraction collection the PTFC-2/8 fraction collector as well as either a PT-SP8 multiple syringe pump, an IPC peristaltic pump or a CAT piston pump can be added to the PTWS 820D. Using the PTWS 820D within an automated system offers the operator full access to the vessels before and at the end of a run as the complete drive head is lifted electronically. Sampling sequence timing is programmed using the menu system of the PTWS 820D, while sampling volume and the optional media refilling process is programmed at either the PTFC 2/8 or DSR-M. No external software is necessary in this system. The motorized sampling system EPE-820 is used to lower the sampling ferrules while sampling into the dissolution vessels.

When sampling is finished the sampling ferrules are raised out of the media and the system waits for the next cycle. Each sampling ferrule holds a 5 or 10µ PP sinter filter. When the tablets have been dropped into the dissolution vessels the automated sampling process starts. If the refilling option is used media refilling will start automatically after a sample has been withdrawn.

It is also possible to use the DSR-M dissolution sampling robot which features the capability of sample dilution and offers excellent sampling accuracy via the fully integration piston pump module. Like the PTFC 2/8, the DSR-M can be fully controlled by the PTWS 820D.

For an online automated system it is possible to use a UV/VIS spectrophotometer with a multiple-cell-changer. The spectrophotometer and pump of such a system is controlled by the powerful WinDiss ARGUS dissolution software. WinDiss ARGUS features drivers for most commonly available UV/VIS spectrometer types, like Agilent 8453 Diode Array, or conventional UV/VIS monochromatic spectrophotometers (preferably double beam and scanning versions) such as the T70, Cecil CE and Perkin Elmer Lambda series as well as drivers for many popular types of pumps. The PTWS 820D can be used in stand-alone mode in these systems.



WinDiss ARGUS Dissolution Software

Advantages

Some of the highlights the PTWS 820D offers are:

- Modular design to minimize bench space requirements
- 3-point individual vessel centering system
- Excellent access to all vessels
- Screen saver functionality offers most important information at a glance (stirrer speed, bath temperature, time to next sampling interval, elapsed time, media temperature etc.)
- Wake up functionality to start heating at a pre-programmed time
- Ultra-fast heating system due to newly designed heat exchanger
- MonoShaft™ system to avoid re-adjustment of immersion depth
- Staggered stirrer start feature for convenient manual sampling
- Water diffuser for even temperature distribution
- Spring loaded pump assembly to eliminate vibration transfer
- Extraordinary safety features for pump and heating system, flow control, digital temperature control, thermo switch, thermo fuse
- Auto stirrer stop when drive list is moved
- Excellent stirrer shaft verticality inside the vessels due to central position of lift columns and drive head assembly
- Easy removal of the water bath from of the frame work for cleaning and maintenance work
- DQ/QC, IQ and OQ documents included free of charge

Features

The main features of the PTWS 820D are:

- Fully USP <711/724> and EP <2.9.3/4> compliant
- 8 stirred positions
- Centrally located motorized lift drive to raise and lower the drive head
- Individually coded Borosilicate vessels
- File up a nearly unlimited number of different test descriptions (methods)
- Instrument suitability check prior to start of a test run
- Staggered start capability
- Vessel low evaporation sealing covers
- Removable water bath for easy cleaning
- Drainage tap to empty the bath
- Method management and user administration
- User Access control, password expiry control
- Optical and acoustic signals to inform about sampling intervals,
- Timer count down function
- Traffic Light optical information on display shows the instrument status by different colors (green = ready to use, yellow = preparing to use, red = error encountered)
- OQ, PQ interval warning with programmable interval
- USB port for remote control of the PTWS 820D
- RS-232 port to connect a serial PT-RP80 report printer, printing date/time, sampling time information, selected sampling position, used stirring tools, media temperature, operator name etc.
- I/O port for remote control of external instruments in automated applications, like DSR-M, Pumps and PTFC-2/8

Standard Scope of Supply

The PTWS 820D comes ready to use with the following standard scope of supply:

- One set of stainless steel paddles
- One set of 1000ml Borosilicate glass vessels
- One set of depth adjustment balls
- One bottle of ALGEX water preservative
- Comprehensive documentation folder including:
  - User manual
  - DQ/QC instrument compliance test certificate
  - IQ documentation
  - OQ documentation
  - Instrument logbook
  - Compliance certificates for vessels and stirring tools

Options

In addition to the standard scope of supply Pharma Test offers a broad range of accessories and options including:

- Direct control of peripheral instruments via I/O port such as PTFC 2/8 fraction collector or DSR-M Sampling Robot
- 2 liter vessel version (can also be used with 1 liter vessels)
- 250 ml Mini Vessel set incl. mini paddle stirrers
- Amber colored vessels for UV sensitive test materials
- Full range of MonoShaft™ stirring tools available
- Full range of certified validation tools available
- EPE-820 motorized sampling system
- ITM-820 media temperature monitoring system
- TM-820 manual tablet drop magazine
- TMA-820 automated tablet drop magazine
- PT-RP80 serial report printer

PT-RP80 Report Printer

Use the PT-RP80 serial report printer to print out the runtime report of the PTWS 820D.

Example Runtime Report

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RUN TIME REPORT
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PHARMA TEST PTWS820D
S/N: 19023
V: 1.00

PRINT DATE/TIME:
01.03.2014 12:31:48
USER NAME: ADMIN
PRODUCT NAME: PRODUCT1
METHOD NAME: METHOD1

BATCH: 1
BATH TEMP NOM.: 37.0
BATH TEMP ACT.: 36.9
LIFT: USP 1
VOLUME: 900ml
DURATION: 0:10
SPEED: 50

I.-COUNT1:    1
I.-DELAY1: 0:01
I.-COUNT2:    1
I.-DELAY2: 0:02
I.-COUNT3:    0
I.-DELAY3: 0:00

TEST STATUS: NO ERRORS

START: 01.03.2014 12:21:08
  END: 01.03.2014 12:31:08


INT.1:
01.03.2014 12:22:08
BATH TEMP ACT.: 36.8

INT.2:
01.03.2014 12:24:08
BATH TEMP ACT.: 36.9



OPERATOR
NAME
.............................


SIGNATURE
.............................
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Type of the instrument (PTWS 820D)
Serial number of the instrument
Firmware version installed on the instrument

Date and time of this print out
Name of the user currently logged in
Name of the product used for this test
Name of the method used for this test

Batch number entered at the start of this test
Nominal bath temperature from the method for this test
Actual bath temperature at time of the print out
Name of the lift position from the method for this test
Media volume from the method for this test
Total duration time setting for the method for this test
Nominal speed setting from the method for this test

First interval count
First interval delay
Second interval count
Second interval delay
Third interval count
Third interval delay

Current status of the test, if test is still running it will be "IN PROGRESS"
Start date and time of the test
End date and time of the test (if already finished)

Occurrence of first interval
Date and time of first interval
Actual bath temperature when first interval occurred

Occurrence of second interval
Date and time of second interval
Actual bath temperature when first interval occurred

If no intervals have yet occurred it will be "NO INT"

Space to write down name of the operator

Space for the operator's signature

Technical Data (Standard 1 Liter Version)

Parameter	Specification
Display	6", 320x240 pixel color LCD, illuminated
Data Entry	Resistive touch screen, functional touch keys
Acoustic Signal	Programmable acoustic signal for operator information
Timer	Programmable sampling times, wake-up and sleeping mode, operation time information and timer count-down mode
Stirrer Position	8 programmable stirrer immersion positions (paddle over disk, transdermal cylinder etc.)
Testing Method Descriptions	Unlimited number of different test descriptions can be stored on SD card
User Access Control	Multiple level access control, password expiry date control
OQ, PQ control	Programmable time periods to remind on QO or PQ testing
Printer	External PT-RP80 report printer
Number of Stirred Vessels	8 (4 by 2 or 2 by 4 arrangement)
Standard Vessels	1 liter USP/EP Borosilicate glass vessel, each individually coded
Speed Control	25 - 250 RPM
Speed Accuracy	±2% of set speed, typically < 1%
Stirrer Shaft Wobble	Better than 0.2 mm total run out
System Tools	MonoShaft™ stirrer design, USP/EP apparatus 1, 2, 5, 6 tool adapter, cream cell, transdermal patch tools, each tool and vessel individually coded
Heating System	Pump for water circulation and 1400W heater for fast heating up
Heater Range	25 - 45°C
Heater Accuracy	± 0.2°C inside the water bath
Heat Up Process	Energy saving, programmable “wake up” heater function and “sleep mode”
Water Circulation	Water circulated from external heating system through special diffuser inside the water bath
Vibration Elimination	External heating system, spring loaded pump assembly
Calibration	Built-in calibration procedures for speed, temperature control, OQ/PQ interval programmable including alarm indicator
Bench Space Requirement	45 x 75 cm (2 by 4) or 75 x 45 cm (4 by 2)
Certification	All components certified to USP / EP requirements
CE / EMC Certification	All CE / EMC Certification provided
Validation	All IQ & OQ documents included

We reserve the right to make technical changes without any prior notice.